UNITED STATES DISTRICT COURT

for the

Western District of Washington

In the Matter of the Search of *(Briefly describe the property to be searched or identify the person by name and address)* Information associated with one target account that is stored at premises controlled by Google LLC, as more fully described in Attachment A	)	Case No. MJ24-045

APPLICATION FOR A SEARCH WARRANT

I, a federal law enforcement officer or an attorney for the government, request a search warrant and state under penalty of perjury that I have reason to believe that on the following person or property *(identify the person or describe the property to be searched and give its location):*

See Attachment A, incorporated herein by reference.

located in the Northern District of California, there is now concealed *(identify the person or describe the property to be seized)*:

See Attachment B, incorporated herein by reference.

The basis for the search under Fed. R. Crim. P. 41(c) is *(check one or more)*:

- ☑ evidence of a crime;
- ☐ contraband, fruits of crime, or other items illegally possessed;
- ☑ property designed for use, intended for use, or used in committing a crime;
- ☐ a person to be arrested or a person who is unlawfully restrained.

The search is related to a violation of:

Code Section	*Offense Description*
21 U.S.C. §§ 331(a), (d), (k), and (i)	Introduction of Misbranded Drug into Interstate Commerce; Introduction of Unapproved New Drugs into Interstate Commerce; Drug Misbranded While Held for Sale After Shipment in Interstate Commerce; and Sale or Dispensing of Counterfeit Drug

The application is based on these facts:

✓ See Affidavit of FDA-OCI SA Angela Zigler, continued on the attached sheet.

☐ Delayed notice of _____ days (give exact ending date if more than 30 days: _____) is requested under 18 U.S.C. § 3103a, the basis of which is set forth on the attached sheet.

Pursuant to Fed. R. Crim. P. 4.1, this warrant is presented: ☑ by reliable electronic means; or: ☐ telephonically recorded.

Applicant's signature

Angela Zigler, Special Agent

Printed name and title

◉ The foregoing affidavit was sworn to before me and signed in my presence, or
○ The above-named agent provided a sworn statement attesting to the truth of the foregoing affidavit by telephone.

Date: 1/25/2024

Judge's signature

City and state: Seattle, Washington

Hon. S. Kate Vaughan, United States Magistrate Judge

Printed name and title

AFFIDAVIT OF ANGELA ZIGLER

STATE OF WASHINGTON)

) ss

COUNTY OF KING)

I, Angela Zigler, being duly sworn, depose and state as follows:

PURPOSE OF AFFIDAVIT

1. I make this Affidavit in support of an application for a search warrant for information associated with email account [redacted]@gmail.com (referred to as the SUBJECT EMAIL ACCOUNT) that is stored at premises controlled by Google, an email provider headquartered at 1600 Amphitheatre Parkway, Mountain View, CA 94043. The information to be searched is described in the following paragraphs and in Attachment A. I am applying for a search warrant under 18 U.S.C. 2703(a), 2703(b)(1)(A) and 2703(c)(1)(A) to require Google to disclose to the government copies of the information (including the content of communications) further described in Section I of Attachment B. Upon receipt of the information described in Section I of Attachment B, government-authorized persons will review that information to locate the items described in Section II of Attachment B.

2. As described in greater detail below, investigative efforts to date indicate that [redacted], an individual based in Mexico, is unlawfully smuggling adulterated, misbranded, and counterfeit prescription drugs from Mexico and selling them to purchasers in the United States. Over the course of the investigation, [redacted] has used the SUBJECT EMAIL ACCOUNT to conduct business operations associated with his pharmaceutical fraud scheme to smuggle adulterated, misbranded, and counterfeit prescription drugs into the United States, and to unlawfully wholesale prescription drugs without a license to unauthorized trading partners.

3. The facts set forth in this Affidavit are based on my personal knowledge and knowledge obtained from other individuals during my participation in this investigation, including other agents; review of documents and records related to this investigation;

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communications with others who have personal knowledge of the events and circumstances described herein; and information gained through my training and experience. Because this Affidavit is submitted for the limited purpose of establishing probable cause in support of the application for a search warrant, it does not set forth each and every fact that I, or others, have learned during the course of this investigation.

4. Based on my training and experience and the facts as set forth in this Affidavit, there is probable cause to believe that violations of Title 21, United States Code, Section 331(a) (Introduction of a Misbranded Drug into Interstate Commerce); Title 21, United States Code, Section 331(d) (Introduction of Unapproved New Drugs into Interstate Commerce); Title 21, United States Code, Section 331(k) (the doing of any act which results in a drug being misbranded while held for sale after shipment in interstate commerce); and Title 21, United States Code, Section 331(i) (the Sale or Dispensing of a Counterfeit Drug) have been committed by [redacted] There is also probable cause to search the information described in Attachment A for evidence, instrumentalities, or fruits of these crimes, further described in Attachment B.

INTRODUCTION AND AGENT BACKGROUND

5. I am a Special Agent with the Food and Drug Administration (FDA) Office of Criminal Investigations (OCI) and have been so employed since November 2012. As such, I am responsible for investigating criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 et seq.; the Controlled Substances Act, 21 U.S.C. §§ 801 et seq.; the Public Health Service Act (PHSA), 42 U.S.C. §§ 201 et seq.; and related violations within Title 18 of the United States Code. From February 2008 through November 2012, I served as a Special Agent with the U.S. Department of Treasury, Treasury Inspector General for Tax Administration. My professional and academic training includes intensive training at the Federal Law Enforcement Training Centers in Glynco, GA and Charleston, SC. Additionally, I have completed the Basic Investigative Electronics Training Program and the Pharmaceutical Fraud Training Program.

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6. During my law enforcement career, I have conducted and participated in federal criminal investigations involving but not limited to pharmaceutical fraud, financial fraud, extortion, conflict of interest violations, obstruction of tax administration, and unauthorized access to government computers. I have participated in the execution of search warrants on businesses and residences in connection with suspected mail fraud, wire fraud, and the introduction of misbranded and/or adulterated drugs, devices, and/or food. I have also participated in executing arrest warrants in pharmaceutical fraud investigations.

APPLICABLE LAWS

7. The FDA is charged with protecting the health and safety of the public by enforcing the FDCA. One purpose of the FDCA is to ensure that drugs sold for use by humans are safe, effective, and bear labeling containing only true and accurate information. The FDA's responsibilities include regulating the distribution and labeling of prescription drugs shipped or received in interstate commerce.

8. Under the FDCA, "label" means "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The FDCA's requirement that any word, statement, or other information appear on the label is satisfied only if the word, statement, or other information also appears on the outside container or wrapper, if such exists, of the retail package of such article, or is easily legible through the outside container or wrapper. *Id*. "Labeling" is defined more broadly, and includes all labels and other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

9. The "intended use" of an article means the objective intent of the persons legally responsible for the labeling of that article. The intent is determined by such persons' expressions or can be shown by the circumstances surrounding the distribution of the article. This objective intent might, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It might be shown by the circumstances that

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the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it was neither labeled nor advertised. 21 C.F.R § 201.128.

10. Under the FDCA, "drugs" are defined as, among other things, articles intended for use in the cure, mitigation, treatment or prevention of disease (21 U.S.C. § 321(g)(a)(B)); articles (other than food) intended to affect the structure or function of the human body (21 U.S.C. § 321(g)(1)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)).

11. A "new drug" is any drug which is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 321(p)(1). In order to be lawfully introduced or delivered into interstate commerce, a new drug had to be the subject of a New Drug Application approved by the FDA. 21 U.S.C § 355.

12. Under the FDCA, a "prescription drug" is any drug intended for use in humans that, because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or a drug which is limited by a legally approved application (under 21 U.S.C. § 355) for use under the professional supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1).

13. Under the PHSA, a "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i). Under the PHSA, no person shall introduce or deliver for introduction into interstate commerce any biological product unless a biologics license is in effect for the biological product; and each package of the biological product is plainly marked with the proper name of the biological product contained in the package; the name, address, and

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applicable license number of the manufacturer of the biological product; and the expiration date of the biological product. 21 U.S.C. § 262(a).

14. Many products meet the definitions of both drugs and biological products. The FDCA applies to a biological product subject to regulation under Title 42, except that a product for which a biological license has been approved under subsection 42 U.S.C. § 262(a) is not required to have an approved new drug application under 21 U.S.C. § 355. 42 U.S.C. § 262(j).

15. Owners and operators of any establishment in any State where drugs are manufactured must register each such establishment with FDA. 21 U.S.C. § 360(b) & (c). Likewise, foreign establishments must be similarly registered with FDA before they import drugs from such establishments into the United States. 21 U.S.C. § 360(i). They must also list with FDA all the drugs (bi-annually) that they produce. 21 U.S.C. § 360(j).

16. For the purposes of determining whether someone must register as a drug manufacturer, "manufacturing" includes, among other things, not just processing of raw materials into finished drug products, but also relabeling, repacking, repackaging, salvaging, or otherwise changing the container, wrapping or labeling of any drug package to further the distribution of the drug from the original manufacturer to the ultimate consumer. Relabel means to change the existing label or labels on a drug or drug package, or change or alter the existing labeling for a drug or drug package, without repacking the drug or drug package. Repack or repackage means the act of taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug. 21 U.S.C. § 360(a)(1); 21 C.F.R. §§ 207.1; 207.9(a); and 207.17.

17. A drug is adulterated if, among other things,

a. it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health (21 U.S.C. § 351(a)(2)(A)); or

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b. any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor (21 U.S.C. § 351(d)).

18. A drug is misbranded if, among other things:

a. The labeling is false or misleading in any particular (21 U.S.C. §352(a));

b. It is a prescription drug and was dispensed without a valid prescription written by a licensed medical practitioner (21 U.S.C. § 353(b)(1));

c. It was manufactured in an establishment not duly registered with FDA as required by 21 U.S.C. § 360 (21 U.S.C. § 352(o)); or

d. The labeling lacks adequate directions for use[1] (21 U.S.C. § 352(f)(1)).

19. The FDCA was amended by the Drug Supply Chain Security Act (DSCSA) in 2013 to address prescription drug diversion (where prescription drugs were removed from the regulated distribution channels and subsequently reintroduced into the wholesale marketplace through various means) and the introduction of prescription drugs into the US marketplace from unknown sources. Under the DSCSA:

a. "Wholesale Distribution" means distribution of a prescription drug to or receipt of a prescription drug by a person other than a consumer or patient, but does not include the lawful dispensing of a prescription drug to a consumer pursuant to a valid prescription according to 21 U.S.C. § 353(b)(1). No person may engage in wholesale distribution of a prescription drug in any State unless such person is licensed by the State from which the drug is distributed; or if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State. 21 U.S.C. § 353(e).

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[1] "Adequate directions for use" means directions under which the layperson can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Directions under which the layperson can use a prescription drug safely cannot be written because such drugs can only be used safely, if at all, at the direction, and under the supervision, of a physician. There are some exemptions from this general requirement for approved prescription drugs with their approved labeling, but no such exemptions exist for a drug lacking an FDA approval.

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b. A "wholesale distributor" of prescription drugs means a person (other than the manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution. 21 U.S.C. § 360eee(29).

c. A "dispenser" means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

d. The term "trading partner" means, among other things, a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product. 21 U.S.C. § 360eee(23).

e. "Transaction" means the transfer of product between persons in which a change of ownership occurs. 21 U.S.C. § 360eee(24).

f. "Authorized" means:

i. in the case of a manufacturer or repackager, having a valid registration in accordance with 21 U.S.C. § 360;

ii. in the case of a wholesale distributor, having a valid license under a State law or 21 U.S.C. § 360eee-2, in accordance with 21 U.S.C. § 360eee-1(a)(6); or

iii. in the case of a dispenser, having a valid license under State law. 21 U.S.C. § 360eee(2).

g. "Licensed," in the case of a wholesale distributor, means having a valid license in accordance with 21 U.S.C. § 353(e) or a State law. 21 U.S.C. § 360eee(9).

20. Among other things, no person can lawfully engage in wholesale distribution of prescription drugs in interstate commerce unless such person is licensed by the State into which the drug is distributed, if the State into which the drug is distributed requires the licensure of a

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person distributing prescription drugs into the State. 21 U.S.C. § 353(e)(1)(A). Moreover, wholesale distributors and dispensers may only lawfully sell to or purchase from an authorized trading partner. 21 U.S.C. §§ 360eee-1(c)(3) and (d)(3).

21. Under 21 U.S.C. § 331, the doing or causing of any of the following are prohibited:

a. the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug (21 U.S.C. §331(a)).

b. the introduction or delivery for introduction into interstate commerce of any unapproved new drug (21 U.S.C. § 331(d)).

c. The doing of any act, including dispensing a prescription drug without a valid prescription, which results in the drug being misbranded while held for sale after shipment in interstate commerce (21 U.S.C. § 331(k)).

d. the doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug (21 U.S.C. § 331(i)).

e. The failure to comply with the requirements of 21 U.S.C. § 360eee–1 by conducting a transaction involving prescription drugs with an unauthorized trading partner (21 U.S.C. §§ 331(t)).

f. the unlicensed wholesale distribution of prescription drugs in violation of 21 U.S.C. § 353(e). 21 U.S.C. § 331(t).

22. Any person who violates a provision of Section 331 shall be imprisoned for not more than one year or fined not more than $200,000, or both. 21 U.S.C. § 333(a)(1); 18 U.S.C. §§ 3571(b)(5) and (c)(5). If any person commits such a violation after a conviction under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $500,000, or both. 21 U.S.C. § 333(a)(2); 18 U.S.C. § 3571(b)(3) and (c)(3).

23. Notwithstanding 333(a), any person who

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a. violates 21 U.S.C. § 331(t) by knowingly distributing prescription drugs in violation of 21 U.S.C. § 353(e)(1) shall be imprisoned for not more than 10 years or fined not more than $250,000, or both. 21 U.S.C. § 333(b)(1)(D).

b. violates 21 U.S.C. § 331(i)(3) by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug shall be imprisoned for not more than 10 years or fined in accordance with Title 18, or both. 21 U.S.C. §333(b)(8).

24. Any person who fraudulently or knowingly and intentionally adulterates a drug such that the adulterated drug has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both. 21 U.S.C. § 333(b)(7).

BACKGROUND ON INVESTIGATION AND THE DRUGS INVOLVED

25. Keytruda® (pembrolizumabis) is the name of a prescription drug licensed as a biological by the FDA for distribution in the United States to treat late stage cancer. Merck & Co., Inc. manufactures Keytruda® and its active ingredient, pembrolizumab, and has the exclusive right to manufacture Keytruda® marketed in the United States. Keytruda® is a registered trademark of Merck Sharp & Dohme Corporation, a subsidiary of Merck & Co., Inc. Keytruda® is an intravenous drug sold in vials and with packaging bearing markings that are also registered as trademarks of Merck and its subsidiaries. Accompanying the Keytruda® vials and packaging are patient safety information, approved by the FDA, bearing registered trademarks owned by Merck and its subsidiaries. These marks are used by Merck and its subsidiaries and registered by Merck and its subsidiaries on the principal register of the United States Patent and Trademark Office.

26. Invanz® is the name of an FDA-approved prescription infusion drug that is a penem antibacterial indicated in adult patients and pediatric patients (3 months of age and older) for the treatment of the following moderate to severe infections caused by susceptible bacteria:

a. Complicated intra-abdominal infections.

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b. Complicated skin and skin structure infections, including diabetic foot infections without osteomyelitis.

c. Community-acquired pneumonia.

d. Complicated urinary tract infections including pyelonephritis.

e. Acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynecologic infections.

f. In adults, for the prophylaxis of surgical site infection following elective colorectal surgery.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Invanz® and other antibacterial drugs, Invanz® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Invanz® is a registered trademark of Merck & Co., Inc. Invanz® packaging bears markings that are also registered as trademarks of Merck & Co., Inc.. Accompanying the Invanz® packaging are patient safety information, approved by the FDA, bearing registered trademarks owned by Merck & Co., Inc. These marks are used by Merck & Co., Inc. and registered by Merck and its subsidiaries on the principal register of the United States Patent and Trademark Office.

27. Gardasil®9 is the name of a prescription drug licensed by FDA as a biological (vaccine) that helps protect individuals ages 9 to 45 against the following diseases caused by 9 types of Human Papillomavirus: cervical, vaginal, and vulvar cancers in females, anal cancer, certain head and neck cancers, such as throat and back of mouth cancers and genital warts in both males and females. Gardasil®9 is a registered trademark of Merck & Co., Inc. Gardasil9® packaging bears markings that are also registered as trademarks of Merck & Co., Inc. Accompanying the Gardasil®9 packaging are patient safety information, approved by the FDA, bearing registered trademarks owned by Merck & Co., Inc. These marks are used by Merck & Co., Inc. and registered by Merck and its subsidiaries on the principal register of the United States Patent and Trademark Office.

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28. Ibrance® is the name of an FDA-approved prescription drug used in adults to treat HR+, HER2- breast cancer that has spread to other parts of the body (metastatic) in combination with an aromatase inhibitor as the first hormonal based therapy, or fulvestrant in people with disease progression following hormonal therapy. Ibrance® is a registered trademark of Pfizer Inc. Accompanying the Ibrance® packaging are patient safety information, approved by the FDA, bearing registered trademarks owned by Pfizer Inc. These marks are used by Pfizer Inc. and registered by Pfizer and its subsidiaries on the principal register of the United States Patent and Trademark Office.

29. Mpiravir is the name of a drug that has no approval for use for any indication in the United States. The drug is labeled as containing Molnupiravir, the active ingredient in an anti-viral prescription drug manufactured by Merck, which received Emergency Use Authorization (EUA) from FDA for treating mild to moderate COVID-19 in December 2021, and in two other anti-virals which received EUAs from FDA in 2023. Most products labeled as Mpiravir appear to originate from India.

30. Prolia® (denosumab) is the name of an FDA-approved prescription drug indicated for the treatment of certain types of osteoporosis. Prolia® is a registered trademark of Amgen, Inc. Prolia® packaging bears markings that are also registered as trademarks of Amgen, Inc. Accompanying the Prolia® packaging are patient safety information, approved by the FDA, bearing registered trademarks owned by Amgen, Inc. These marks are used by Amgen, Inc. and registered by Amgen, Inc. on the principal register of the United States Patent and Trademark Office.

31. Isentress® is the name of an FDA-approved prescription drug used with other antiretroviral medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults, and in children weighing at least 4.4 pounds. Isentress® is a registered trademark of Merck & Co., Inc. Isentress® packaging bears markings that are also registered as trademarks of Merck & Co., Inc. Accompanying the Isentress® packaging are patient safety information, approved by the FDA, bearing registered trademarks owned by Merck & Co., Inc. These marks are used by

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Merck & Co., Inc. and registered by Merck and its subsidiaries on the principal register of the United States Patent and Trademark Office.

32. In November 2022, I received information from Homeland Security Investigations (HSI), Seattle, that [redacted], an individual based in Mexico, was selling misbranded prescription drugs and unlawfully shipping them from Mexico to purchasers in the United States. HSI had received information from Investigative Consultants (IC), an independent investigative company that works with drug manufacturers to identify counterfeit, mislabeled, and adulterated drugs. According to HSI, IC investigators conducted multiple undercover purchases of prescription drugs from [redacted], and associate [redacted], who is also based in Mexico, from February 8, 2021, to the present. These transactions were facilitated by in-person conversations, email communications, and text messages. Some of the prescription drugs received from these undercover purchases included purported Keytruda and purported Invanz.

33. As set forth below, there is probable cause to believe that [redacted] is using the email account in furtherance of the crimes under investigation.

FACTS ESTABLISHING PROBABLE CAUSE

Initial Independent Investigation

34. On November 29, 2022, an investigator employed by IC provided me detailed written investigative reports, including WhatsApp communications and photographs, of undercover purchases/communications between an IC investigator, [redacted] an [redacted] from February 2, 2021, through November 17, 2022. The information regarding the IC investigator's contacts with [redacted] in this affidavit are based on my review of those reports.

35. On February 2, 2021, an IC investigator observed a post, dated December 2, 2020, on the public Facebook group [redacted] offering the sale of Keytruda 100mg in Guadalajara, Jalisco by a Facebook user, who identified himself as [redacted]. The investigator sent a direct message to [redacted] via Facebook messenger and

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inquired about the Keytruda 100mg. [redacted] responded that the medication was still available. On February 3, 2021 [redacted] provided the investigator with WhatsApp telephone number [redacted] Later that day, the IC investigator contacted the seller via the WhatsApp telephone number. The seller provided the undercover investigator photographs of the Keytruda 100mg.

36. As previously described, Keytruda® is the brand name of a prescription oncology drug which is licensed as a biological by the FDA for distribution within the United States. Other variants of Keytruda, or other drugs containing pembrolizumab, which have not been examined by the FDA and determined safe and effective for the intended medical indications described in its labeling, and which are not the subject of an FDA approved biological license application, are considered new drugs. Because these drugs meet the definition of a new drug, and they lack the required approval or licensing for such drugs, their introduction into interstate commerce violates 21 U.S.C. § 331(d). Other variants (e.g., Merck's Keytruda® drugs intended for sale in Mexico) have not been evaluated by the FDA. They have not been determined to be safe or effective for the intended medical indications described in the labeling and packaging materials. They are categorized as new drugs for regulatory purposes.

37. On February 8, 2021, the IC investigator placed an order via WhatsApp telephone number [redacted] for the prescription drug Keytruda 100mg. A prescription was not requested or provided to complete the order. The seller asked the investigator to send payment before or at the same time the product was shipped. On February 9, 2021, the investigator advised the seller that payment would need to be sent through MoneyGram and the investigator would send half of the payment that day and half the following day. The seller agreed to the payment terms and asked the investigator to send the money to the name of [redacted] which the investigator did. On February 10, 2021, the investigator returned to a MoneyGram retail location and sent the remaining payment to [redacted] who the seller identified as his wife.

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38. On February 10, 2021, the package, containing the Keytruda 100mg, was delivered to an address provided by the investigator in California. The Keytruda was then provided to the Forensic Services Laboratory (FSL) at Merck, West Point, PA, which received it on March 19, 2021. The FSL report concluded that the packaging materials as well as the contents of the shipped package were counterfeit. According to the report: "There were multiple counterfeit defects identified on the carton, vial label and patient insert. They are each concluded to be counterfeit." For example, the authentic Mexican Keytruda labels have a space before the last 'e' in "Pembrolizumab e" and the labeling for the counterfeit Keytruda does not, and was printed "Pembrolizumabe." The chemical analysis of the package contents concluded that Keytruda's active ingredient, "pembrolizumab", was absent.

39. On March 15, 2021, a different IC investigator contacted [redacted] via Facebook Messenger regarding the Keytruda that [redacted] was offering for sale on the Facebook Marketplace. On March 16, 2021, the investigator obtained a WhatsApp telephone number [redacted] for direct communications with [redacted] Between March 16, 2021, and March 24, 2021 [redacted] sent photographs of products labeled as Keytruda, Pfizer's Covid-19 Vaccine, and Remdesiver injection 100mg/20ml[2] that he had available for sale. The investigator also arranged to meet and purchase two Keytruda 100mg vials from [redacted] in the city of Guadalajara, Jalisco, Mexico.

40. On March 27, 2021, the investigator traveled to the parking lot of a Coppel Department Store in the city of Guadalajara. The investigator met with [redacted] and a second individual, who did not identify himself. [redacted] arried a shoe box which contained two vials of Keytruda 100mg and cold packs that the investigator purchased for $2,500 in US currency and $71,995 in Mexican currency, totaling approximately $6,240 USD. A prescription was not requested or provided to complete the order.

[2] Veklury®, manufactured by Gilead Sciences, Inc., is an FDA-approved prescription drug containing the active ingredient remdesivir. It was approved in October 2020 as one of the earliest treatments for COVID-19.

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41. The two vials of purported Keytruda 100mg (marked as an unapproved Merck drug intended for distribution in Mexico) were provided to Merck for analysis. Merck received the Keytruda on April 16, 2021. The Merck FSL report concluded that the packaging materials as well as the contents of the shipped package were counterfeit. According to the report: "There were multiple counterfeit defects identified on the cartons, patients inserts and vial labels. They are each concluded to be counterfeit." For example, the word "células" on the labeling of authentic Mexican Keytruda was printed as "célular" on the counterfeit Keytruda. The chemical analysis of the package contents concluded that Keytruda's active ingredient, "pembrolizumab", was absent.

42. Between April 1, 2021, and April 7, 2021, the IC investigator communicated with [redacted] via WhatsApp telephone number [redacted] During these conversations, [redacted] informed the investigator that he lent his phone out to someone who had now obtained the investigator's number. [redacted] informed the investigator someone might message the investigator saying that they are "the Doctor" but not to believe them.

43. On April 7, 2021, the investigator received a separate message from an individual who identified himself as [redacted] using WhatsApp telephone number [redacted] offered prescription drugs for sale to the investigator.

44. Between April 8, 2021, and April 12, 2021, the investigator communicated with [redacted] ia WhatApp. [redacted] offered Keytruda, Invanz, and other various prescription drugs for sale. During these conversations, the investigator asked [redacted] (in Spanish) how he/she would know that [redacted] was a doctor? [redacted] replied (in Spanish), "Remember the guy who showed up with [redacted]" and "I'm the Doctor why do you think he gave me the money after you paid him when we met." The investigator agreed to purchase one Keytruda 100mg and four Invanz 1g from [redacted] and sent a bank wire to "[redacted]" for $3,380.44 USD (approximately MX$65,500). A prescription was not requested or provided to complete the order.

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45. Following the order, a package was shipped via DHL tracking number [redacted] from Mexico to California and declared as "HEALING MATERIAL." On April 14, 2021, this package was received by the investigator in California.

46. On April 28, 2021, the purported Keytruda and Invanz (both marked as intended for distribution in Mexico) were received by Merck for analysis. According to the analytical report prepared by Merck's FSL regarding the Keytruda product: "There were multiple counterfeit defects identified on the carton, vial label and patient insert. They are each concluded to be counterfeit." For example, the word "células" on the labeling of authentic Mexican Keytruda was listed as "célular" on the counterfeit Keytruda. In addition the words "Medicamento de alto" on the labeling of authentic Mexican Keytruda was printed as "Medicamento de Alto" on the counterfeit Keytruda. The chemical analysis of the package contents concluded that Keytruda's active ingredient, "pembrolizumab", was absent. According to the analytical report prepared by Merck's FSL regarding the Invanz product: "There were multiple counterfeit defects identified on the cartons, patient inserts and vial labels. They are each concluded to be counterfeit." The chemical analysis concluded that the "products were found to be inconsistent with the similarly treated authentic material and are determined to be counterfeit."

47. From the period of April 2021 to August 2022, the IC investigator continued to communicate with [redacted] making four additional undercover purchases for prescription drugs via WhatsApp number [redacted] During these communications, [redacted] indicated that he is selling and sending prescription drug products to a female in California, and that he is also selling controlled substances and sending to California.

48. During the purchase of purported Keytruda 100mg, on or about June 16, 2021, the IC investigator requested a receipt for the purchase. [redacted] from email address [redacted] emailed a receipt to the IC investigator.

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49. On September 11, 2022, [redacted] sent a WhatApp Message to the investigator using a new WhatApp telephone number [redacted] Undercover communications between the investigator and [redacted] continued utilizing this new WhatsApp number.

HSI/FDA Investigation Commences

50. In January 2023, the FDA-OCI initiated an investigation into [redacted]

51. From January 27, 2023, through February 7, 2023, the IC investigator (acting in an undercover capacity) arranged to purchase the drugs represented to be Keytruda 100mg, Invanz 1g, Gardasil9 (Human Papillomavirus 9-valent vaccine), Ibrance (drug used to treat breast cancer), Mpiravir 200mg (for the treatment of mild-to-moderate coronavirus disease) and Prolia 60mg (a drug used to treat osteoporosis) from [redacted] via WhatsApp number [redacted] A prescription was not requested or provided to complete the order. Payment for these medications, in the amount of $4,859.50 USD (approximately MX$87,000) was wired to [redacted] in Mexico on February 2, 2023.

52. Pursuant to this order, a package was shipped from Mexico to Kent, Washington via DHL tracking numbe[redacted], declared as "HEALING MATERIAL." The package contained drugs labeled as Keytruda 100mg, Invanz 1g, Gardasil9, Ibrance, Mpiravir 200mg and Prolia 60mg.

53. On February 14, 2023, the Keytruda, Invanz and Gardasil9 were sent to Merck for analysis. The Ibrance, Mpiravir, and Prolia were sent to the FDA Forensic Chemistry Center (FCC) for analysis.

54. On March 31, 2023, I received the analytical results from Merck regarding the Keytruda 100mg (labeled as an unapproved Merck product intended for distribution in Turkey). According to the report for the Keytruda: "There were multiple counterfeit defects identified on the carton, tamper-evident seals, vial label, flip cap, metal seal, stopper and vial. They are each concluded to be counterfeit." The chemical analysis of the package contents concluded that Keytruda's active ingredient, "pembrolizumab", was absent.

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55. On May 30, 2023, I received the results from the FDA FCC regarding Ibrance, Mpiravir and Prolia. Each drug was consistent with having the presence of its labeled active ingredient.

56. On December 5, 2023, I received the results from Merck reports for Invanz (labeled as unapproved Merck product intended for distribution in Mexico) and Gardasil9 (labeled as unapproved Merck product intended for distribution in India). Each drug was consistent with having the presence of its labeled active ingredient.

57. On May 10, 2023, the IC investigator (acting in an undercover capacity) introduced [redacted] acting in an undercover capacity) to [redacted] via a WhatApp audio call. The purpose of the call was to introduce [redacted] as another individual who would purchase medications from [redacted]

58. During the time period of June 1, 2023, and June 9, 2023, [redacted] communicated with [redacted] via WhatsApp and placed an order for the following medications: Gardasil9, Isentress 400mg, Keytruda 100mg and alprazolam (the active ingredient in some FDA-approved prescription drugs, like Xanax®, used to treat anxiety disorders, and a Schedule IV Controlled Substance). A prescription was not requested or provided to complete the order.

59. On June 9, 2023, I (acting in an undercover capacity as Angela) wired $4,275 (including $75 bank wire fee) to the bank account of [redacted] in Guadalajara, Jalisco, Mexico for these drugs.

60. On June 13, 2023, and June 19, 2023 [redacted] attempted to ship the drugs via DHL tracking numbers [redacted]. Each time the package was returned to the sender due to the shipment containing the controlled substance alprazolam.

61. On July 4, 2023, [redacted] shipped the drugs, without the alprazolam, to an undercover address in Kirkland, WA via DHL tracking [redacted].

62. On July 6, 2023, the undercover order arrived at the provided address in Kirkland, WA. The package was declared as "HEALING MATERIAL," and contained the following three drugs:

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a. One red box labeled as Gardasil9 (Human Papillomavirus 9-valent vaccine) containing 0.5ml single-dose prefilled syringe. The box was also labeled "Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only" and "For sale in India only- Not for Export."

b. One box of drugs labeled in Spanish as Isentress 400mg (Raltegravir) containing 60 tablets per box, and also labeled in Spanish "Your purchase requires a medical prescription."

c. One box labeled as Keytruda 100mg (Pembrolizumab injection) single dose vial (English writing), and "Rx only."

63. I sent the above items to Merck for analysis on July 11, 2023. On August 1, 2023, I received the analytical results from Merck's FSL regarding the Keytruda 100mg (labeled as intended for distribution in Turkey). According to the report for the Keytruda: "There were multiple counterfeit defects identified on the carton, tamper-evident seals (TES), vial label, flip cap, metal seal, stopper, and vial. They are each concluded to be counterfeit." The chemical analysis of the package contents concluded that Keytruda's active ingredient, "pembrolizumab", was absent.

64. On August 8, 2023, I received the results for the drugs labeled as Isentress 400mg (intended for distribution in Mexico) and Gardasil9 (intended for distribution in India) from Merck. Each drug was consistent with having the presence of its labeled active ingredient and found to be consistent with the authentic material.

65. The [redacted] cting in an undercover capacity as [redacted] had his/her last communication with [redacted] in August 2023. At that time, it was determined that all undercover contacts with [redacted] would be conducted by the IC investigator (in an undercover capacity) at the direction of law enforcement.

66. From September 21, 2023, through October 4, 2023, the IC investigator communicated with [redacted] via multiple telephone calls, via WhatsApp number [redacted]

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During this time, the investigator placed an order for two Keytruda 100mg (English writing) and two Invanz 1g.

67. On September 25, 2023, the IC investigator, acting in an undercover capacity, communicated via a recorded audio chat wit During the call, informed the IC investigator that he would email a receipt for this purchase. also informed the IC investigator that he sold Clonazepam (a Schedule IV Controlled Substance) tablets in the past and that dogs were unable to detect these tablets because they were odorless. lso advised that he had previously sent up to 10 boxes of Clonazepam tablets to customers in the U.S., and that he had a female contact at .

68. On September 25, 2023, from email address which is the SUBJECT EMAIL ACCOUNT, sent the IC investigator an email that included a breakdown of what was purchased. The email included the quantity, drug name and price (in pesos), listing each "Keytruda solucion 100mg/4ml" at MX$37,000, "Invanz solucion 1g" at MX$1,500, and parcel shipping at MX$5,000, totaling MX$82,000 (the equivalent of approximately $4,750.00 USD).

69. On September 27, 2023 from the SUBJECT EMAIL ACCOUNT, sent the IC investigator four photographs containing the following images: two boxes of Invanz and two boxes of Keytruda wrapped in ziplock bags; a DHL box with a shipping label next to it; a DHL box with the shipping label attached to it bearing tracking number and a screenshot of a foreign payment order for the amount MX$152,445.80 (approximately $8,825.00 USD) (the amount that was paid to or this shipment and a future shipment).

70. The package containing two boxes labeled as Keytruda 100mg and two boxes labeled as Invanz 1g were received in Kirkland, WA on October 6, 2023, via DHL tracking number

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71. On October 10, 2023, the above items were sent to Merck's FSL for analysis. On November 14, 2023, I received the analytical results from FSL regarding these products. One box of Invanz (labeled as unapproved Merck product intended for distribution in Mexico) was tested and was consistent with having the presence of its labeled active ingredient and found to be consistent with the authentic material. One box of the Keytruda (bearing English writing and labeled as unapproved Merck product intended for distribution in Turkey) was tested and found to have "multiple counterfeit defects identified on the carton, tamper evident seals, vial label, vial, flip cap, metal seal and stopper. They are each concluded to be counterfeit." The chemical analysis of the package contents concluded that Keytruda's active ingredient, "pembrolizumab", was absent.

FEDERAL VIOLATIONS OF LAW

72. The communications and other events referenced in the preceding paragraphs disclose an apparent prescription drug fraud scheme involving the illegal sale and subsequent smuggling of misbranded, adulterated, and counterfeit prescription new drugs. The drugs purchased and transactions negotiated wi[redacted]ould not legally be sold and imported into the United States.

73. As previously explained, 21 U.S.C. § 331(a) prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded; 21 U.S.C. § 331(d) prohibits the introduction into interstate commerce of an unapproved new drug; 21 U.S.C. § 331(k) prohibits the doing of any act to a drug (including dispensing a prescription drug without a prescription), while the drug is held for sale, which causes the drug to be misbranded; and 21 U.S.C. § 331(i)(iii) prohibits the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug. Probable cause exists to believe that [redacted] has violated these provisions of the FDCA, and that the stored email will contain evidence of these crimes.

BACKGROUND REGARDING GOOGLE'S SERVICES

74. Both before and during this investigation, I learned that Google provides a variety of on-line services to the general public, including email services, typically through gmail.com

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accounts. Google subscribers obtain an account by registering with Google. When doing so, email providers like Google ask the subscriber to provide certain personal identifying information. This information can include the subscriber's full name, physical address, telephone numbers and other identifiers, alternative email addresses, and, for paying subscribers, means and source of payment (including any credit or bank account number). In my training and experience, such information may constitute evidence of the crimes under investigation because the information can be used to identify the account's user or users, and to help establish who has dominion and control over the account.

75. Google typically retains certain transactional information about the creation and use of each account on their systems. This information can include the date on which the account was created, the length of service, records of log-in (i.e., session) times and durations, the types of service utilized, the status of the account (including whether the account is inactive or closed), the methods used to connect to the account (such as logging into the account via Google's website), and other log files that reflect usage of the account. In addition, email providers often have records of the Internet Protocol address ("IP address") used to register the account and the IP addresses associated with particular logins to the account. Because every device that connects to the Internet must use an IP address, IP address information can help to identify which computers or other devices were used to access the email account, which can help establish the individual or individuals who had dominion and control over the account.

76. When the subscriber sends an email, it is initiated at the user's computer, transferred via the Internet to Google's servers, and then transmitted to its end destination. Google often maintains a copy of the email sent. Unless the sender of the email specifically deletes the email from the Google server, the email can remain on the system indefinitely. Even if the sender deletes the email, it may continue to be available on Google's servers for a certain period of time.

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77. A sent or received email typically includes the content of the message, source and destination addresses, the date and time at which the email was sent, and the size and length of the email. If an email user writes a draft message but does not send it, that message may also be saved by Google but may not include all of these categories of data.

78. In some cases, email account users will communicate directly with an email service provider about issues relating to the account, such as technical problems, billing inquiries, or complaints from other users. Email providers typically retain records about such communications, including records of contacts between the user and the provider's support services, as well records of any actions taken by the provider or user as a result of the communications. In my training and experience, such information may constitute evidence of the crimes under investigation because the information can be used to identify the account's user or users.

79. The sought email evidence has not been previously available to me or other agents. On November 17, 2023, I sent a preservation letter to Google requesting that it preserve all evidence related to the email accoun

INFORMATION TO BE SEARCHED AND THINGS TO BE SEIZED

80. Pursuant to Title 18, United States Code, Section 2703(g), this application and Affidavit for a search warrant seeks authorization to permit Google, and its agents and employees, to assist agents in the execution of this warrant. Once issued, the search warrant will be presented to Google with direction that it identify the account described in Attachment A to this Affidavit, as well as other subscriber and log records associated with the account, as set forth in Attachments B to this Affidavit.

81. The search warrant will direct Google to create an exact copy of the specified account and records, which will then be provided to government agents for search.

82. I, and/or other law enforcement personnel, will thereafter review the copy of the electronically stored data and identify from among that content those items that come within the items identified in Section II to Attachment B for seizure.

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83. Analyzing the data contained in the forensic image may require special technical skills, equipment, and software. It could also be very time-consuming. Searching by keywords, for example, can yield thousands of "hits," each of which must then be reviewed in context by the examiner to determine whether the data is within the scope of the warrant. Merely finding a relevant "hit" does not end the review process. Keywords used originally need to be modified continuously, based on interim results. Certain file formats, moreover, do not lend themselves to keyword searches, as keywords, search text, and many common email, database and spreadsheet applications do not store data as searchable text. The data may be saved, instead, in proprietary non-text format. And, as the volume of storage allotted by service providers increases, the time it takes to properly analyze recovered data increases, as well. Consistent with the foregoing, searching the recovered data for the information subject to seizure pursuant to this warrant may require a range of data analysis techniques and may take weeks or even months. All forensic analysis of the data will employ only those search protocols and methodologies reasonably designed to identify and seize the items identified in Section II of Attachments B to the warrant.

84. Based on my experience and training, and the experience and training of other agents with whom I have communicated, it is necessary to review and seize a variety of email communications, chat logs and documents, that identify any users of the subject account and emails sent or received in temporal proximity to incriminating emails that provide context to the incriminating communications.

REQUEST FOR NONDISCLOSURE

85. The government requests by separate motion, pursuant to the preclusion of notice provisions of Title 18, United States Code, Section 2705(b), that Google be ordered not to notify any person (including the subscriber or customer to which the materials relate) of the existence of this warrant for one year. The government submits that such an order is justified because notification of the existence of this warrant would seriously jeopardize the ongoing investigation. Such a disclosure would give the subscriber an opportunity to destroy evidence, change patterns of behavior, notify confederates, or flee.

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CONCLUSION

86. Based on the forgoing, I request that the Court issue the proposed search warrant. This Court has jurisdiction to issue the requested warrant because it is "a court of competent jurisdiction" as defined by 18 U.S.C. § 2711. 18 U.S.C. §§ 2703(a), (b)(l)(A) & (c)(l)(A). Specifically, the Court is "a district court of the United States . . . that has jurisdiction over the offense being investigated." 18 U.S.C. § 2711(3)(A)(i). Accordingly, by this application and Affidavit I seek authority for the government to search all of the items specified in Section I, Attachment B (attached and incorporated by reference), and specifically to seize all of the data, documents, and records that are identified in Section II to that same Attachment.

ANGELA ZIGLER
Special Agent
Food and Drug Administration
Office of Criminal Investigations

The above-named agent provided a sworn statement attesting to the truth of the foregoing affidavit by telephone on the 25th day of January, 2024.

HONORABLE S. KATE VAUGHAN
United States Magistrate Judge

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ATTACHMENT A

Account to be Searched

The electronically stored data, information, and communications contained in, related to, and associated with (including all preserved data associated with) the SUBJECT EMAIL ACCOUNT:

[redacted]

as well as all other subscriber and log records associated with this account, which is located at premises owned, maintained, controlled or operated by Google, an email provider headquartered at 1600 Amphitheatre Parkway, Mountain View, CA 94942.

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ATTACHMENT B

Information to be Seized

1. Information to be Disclosed by Google

To the extent that the information described in Attachment A is within the possession, custody, or control of Google, including any emails, records, files, logs, or information that has been deleted but is still available to Google, or has been preserved pursuant to a request made under 18 U.S.C. § 2703(f) on November 17, 2023, Google is required to disclose the following information to the government for each account or identifier listed in Attachment A:

a. The contents of all emails associated with the account, including stored or preserved copies of emails sent to and from the account, draft emails, the source and destination addresses associated with each email, the date and time at which each email was sent, and the size and length of each email;

b. All records or other information regarding the identification of the account, to include full name, physical address, telephone numbers and other identifiers, records of session times and durations, the date on which the account was created, the length of service, the IP address used to register the account, log-in IP addresses associated with session times and dates, account status, alternative email addresses provided during registration, methods of connecting, log files, and means and source of payment (including any credit or bank account numbers);

c. The types of service utilized;

d. All records or other information stored at any time by an individual using the account, including address books, contact and buddy lists, calendar data, pictures, and files;

e. All subscriber records associated with the specified account including lists of all accounts, any contact lists, and Google Groups content and/or preserved data.

2. Information to be Seized by the Government

All information described above in Section I that constitutes fruits, contraband, evidence, or instrumentalities of violations 21 U.S.C. § 331(a), (d), (k), and (i), those violations occurring

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between **January 1, 2021, and the present**, including, for the account or identifier listed on Attachment A, information pertaining to the following matters:

a. The soliciting, ordering, shipment, importation, exportation, purchase, manufacture, sale, distribution, or storage of drugs, including but not limited to U.S. Customs entry forms; FDA and/or Customs detention, refusal and/or seizure notices, Entry Summaries; US Customs Manifests of goods; U.S. Customs declaration forms; invoices; bills of lading; air way bills; purchase orders; general ledgers; subsidiary ledgers; and packing slips;

b. Financial account records, payments, sale invoices, contracts, agreements, complaints, transactional information, or account ownership information relating t [redacted]

c. Customer or patient lists and address books containing information relating to the shipment, importation, exportation, purchase, manufacture, sale, distribution, dispensing, or storage of prescription drugs, or pills, tablets, capsules, syringes or vials that resemble or appear to be or to contain prescription drugs;

d. Patient Medical Records and/or customer purchase records;

e. All messages, documents, and profile information, attachments, or other data that serves to identify any persons who use or access the specified account, or who exercise in any way any dominion or control over the specified account;

f. Any address lists or buddy/contact lists associated with the specified account;

g. All subscriber records associated with the specified account, including name, address, local and long distance telephone connection records, or records of session times and durations, length of service (including start date) and types of service utilized, telephone or instrument number or other subscriber number or identity, including any temporarily assigned network address, and means and source of payment for such service, including any credit card or bank account number;

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h. All log records, including IP address captures, associated with the specified account;

i. Any records of communications between Google and any person about issues relating to the account, such as technical problems, billing inquiries, or complaints from other users about the specified account. This is to include records of contacts between the subscriber and the provider's support services, as well as records taken by the provider or subscriber as a result of the communications.

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